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EXAMINER

CELSA, BENNETT M

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,502

Applicant(s)

MILLSTEIN, LARRY S.

Examiner

Bennett Celsa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/20/01 6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 1-21 are currently pending.

Claims 1-12 are under consideration.

Claims 13-21 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-12) in the correspondence dated 10/27/03 is acknowledged.

Applicant first argues that there is no showing of a serious search burden to examine all of the claims. This argument is not persuasive for the reasons provided in the lack of unity requirement e.g. on page 2 wherein the different subject matter of the Groups and the lack of a special technical feature necessitates different and separately burdensome searches.

Applicant further argues that the claims reflect unity of invention since claim 1 (e.g. Group I) relates to analytes as does the claims of Group II from which they depend. This argument is not persuasive for the reasons provided in the lack of unity requirement e.g. the lack of a same special technical feature (e.g. Search report and Kramer citations), the methods being directed to different objectives, steps and different and separately burdensome searches.

Applicant further argues that "[T]he product of Group III is not restrictable from a process of preparing it (claim 1) .The same applies to the Group III claims". This

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argument is not persuasive for the reasons provided in the lack of unity e.g. the failure of Groups I-III to share the same or corresponding technical features for the reasons provided thereon.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of antibodies as the species of analyte binding molecule in the correspondence dated 10/27/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The abstract of the disclosure is objected to because This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. The submission of the front page of the WO document is not a proper abstract.

Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (e.g. see specification page 3, line 21). See MPEP § 608.01.

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Appropriate correction is required.

Claim Objections

Claim 4 is objected to because of the following informalities: the incorrect spelling of the term "photactivatable". Appropriate correction is required.

Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 1 is indefinite for the following reasons. The claimed method is directed to making a device (e.g. an array) of immobilized analyte binding molecules: introducing/attaching said analyte binding molecules (e.g. steps a and b) and removing unbound analyte binding molecules (e.g. step c) with the ultimate formation of "an element". The phrase "an element" lacks clear antecedent basis. Additionally, the structure of "an element" lacks metes and bounds, especially regarding structure beyond that resulting from a device having immobilized Analyte binding molecules".
- B. In claim 10, the term "said **photo**activatable surface" lacks clear antecedent basis for the phrase "photo".
- C. In claims 11 and 12, the term "the analyte-**determining** molecule" lacks clear antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 11-12 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated by Winkler et al. US Pat. No. 5,677,195 (10/97: filed 11/92 or earlier).

The presently claimed invention is directed to a method of making a device (e.g. an array) having immobilized in a predetermined pattern a plurality of analyte-binding molecules (e.g. DNA/Proteins, including antibodies: see col. 5-6) etc. comprising:

a. introducing analyte-binding molecules into a plurality of non-communicating channels comprising one or more surfaces that can be activated to immobilize said molecules;

b. selectively activating a part of said one or more surfaces effective to immobilize analyte-binding molecules thereon;

c. removing unbound analyte-binding molecules from said channels

with successive reiteration of steps a, b and c for activating a different part of said one or more surfaces.

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Winkler et al. teach a method and device for forming large arrays (pluralities) of polymers (e.g. oligonucleotides, peptides, including antibodies: e.g. see patent claims) by utilizing a substrate (e.g. see col. 14-16) having channels with reaction sites thereon, which are non-communicating (e.g. see figures: especially figures 1,4,7, 11-13; col. 3, lines 1-32) in which the method employs light-directed methodologies (e.g. see col. 1, citation of Fodor and Pirrung patent references) for polymer attachment. See also Abstract . The polymer arrays may constitute "analytes" e.g. for use "in screening studies for determination of binding affinity". (e.g. see col. 1, especially lines 10-20; col. 5-6). The reference teaches the flowing of reagents through channels formed by the joining of a grooved or channeled block in contact with a derivatized glass other "plastic" (e.g. polystyrene, polycarbonate etc.) substrate to form the channels (e.g. col. 2, especially lines 24-62; col. 14-16) which anticipates claims 2-3. Photoactive coupling of the arrayed polymer, including the use of (cross) linkers and selective irradiation using "masks" (e.g. see bottom of col. 22-col.23), followed by washing , the steps of which are iterative (e.g. reintroduction of analyte-binding molecules, activation, coupling to different surfaces and washing) is taught by this reference. See e.g. col. 3, lines 28-42; col. 8-11; col. 14-16; col. 26-28; patent claims).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al. US Pat. No. 5,677,195 (10/97: filed 11/92 or earlier) and Berger et al. US Pat. No. 5,268,306 (12/93) and/or Kramer et al. US Pat. No. 4,689,310 (8/87).

The presently claimed invention is directed to a method of making a device (e.g. an array) having immobilized in a predetermined pattern a plurality of analyte-binding molecules (e.g. DNA/Proteins, including antibodies etc.: see col. 5-6) comprising:

- a. introducing analyte-binding molecules into a plurality of non-communicating channels comprising one or more surfaces that can be activated to immobilize said molecules;
 - b. selectively activating a part of said one or more surfaces effective to immobilize analyte-binding molecules thereon;
 - c. removing unbound analyte-binding molecules from said channels
- with successive reiteration of steps a, b and c for activating a different part of said one or more surfaces.

Winkler et al. teach a method and device for forming large arrays (pluralities) of polymers (e.g. oligonucleotides, peptides, including antibodies: e.g. see patent claims) by utilizing a substrate (e.g. see col. 14-16) having channels with reaction sites thereon, which are non-communicating (e.g. see figures: especially figures 1,4,7, 11-13; col. 3, lines 1-32) in which the method employs light-directed methodologies (e.g. see col. 1, citation of Fodor and Pirrung patent references) for polymer attachment. See also Abstract . The polymer arrays may constitute "analytes" e.g. for use "in screening

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studies for determination of binding affinity". (e.g. see col. 1, especially lines 10-20; col. 5-6). The reference teaches the flowing of reagents through channels formed by the joining of a grooved or channeled block in contact with a derivatized glass other "plastic" (e.g. polystyrene, polycarbonate etc.) substrate to form the channels (e.g. col. 2, especially lines 24-62; col. 14-16) which anticipates claims 2-3. Photoactive coupling of the arrayed polymer, including the use of (cross) linkers and selective irradiation using "masks" (e.g. see bottom of col. 22-col.23), followed by washing, the steps of which are iterative (e.g. reintroduction of analyte-binding molecules, activation, coupling to different surfaces and washing) is taught by this reference. See e.g. col. 3, lines 28-42; col. 8-11; col. 14-16; col. 26-28; patent claims)

The Winkler et al. reference teaching differs from the presently claimed invention (e.g. claim 10) by failing to teach the formation of the photoactivatable surface by coating a surface with alkylamine-polystyrene and then reacting the amine with NHS-ASA forming a phenylazide containing photoactivatable surface.

However, the Winkler et al. reference teach that glass or polystyrene substrates (e.g. see col. 14) can be coated with alkylamine groups and additionally, the use of (cross) linkers for polymer attachment. See. E.g. col. 10, 23-26.

Further, the use of azide containing photocleavable linkers (e.g NHS-ASA: table I col. 6 in Berger; MABI: table 1, col. 6 Berger and in col. 4 Kramer et al.) for modifying amino containing solid supports to effect receptor (e.g. antibody) attachment for assay use is conventionally known in the art. See e.g. Kramer et al. bottom of col. 1; col. 3-4 and patent claims; Berger et al. col. 3 (lines 30-50); col. 5-6; Table 1 and patent claims).

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Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Winkler et al. reference method to modify its alkylaminepolystyrene coated substrates with azide containing photoactivatable crosslinkers (e.g. NH-ASA, MABI etc) for effecting receptor attachment since the Kramer and/or Berger references teach the advantages of these photocleavable cross-linkers for receptor attachment for in vitro assay use (e.g. immunological).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 703-305-7556. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bennett Celsa
Primary Examiner
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BC
January 20, 2004